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EXAMINER

KRASS, FREDERICK F

ART UNIT PAPER NUMBER

1614

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/072,504

Applicant(s)

HODOSH, MILTON

Examiner

Frederick F. Krass

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3-1-99.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Status of Action

A new ground of rejection, based on newly discovered prior art, follows hereinunder. Because this rejection was not necessitated by Applicant's amendment, this rejection is NON-FINAL.

Claim Informalities

Claim 13 contains an obviously misspelled word. Correction is required.

Utility/Written Description

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1) Claims 1-8 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

While it is of course the goal of all practitioners, preparing a composition to "prevent" dental hypersensitivity is not at this time achievable in any realistic sense. This is supported by the various art cited during the prosecution of this case. See for example Hodosh, "A Superior Densensitizer – Potassium Nitrate", JADA, vol. 88, pp. 831-32 (1974). As stated therein, attempts to eliminate dental

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hypersensitivity have "not been uniformly successful for various reasons." (See page 8 at the top of the righthand column).

Since preparation of a composition to "prevent" dental hypersensitivity is not realistically achievable given the state of the art at this time, it is not a credible or well-established utility.

2) Claims 1-8 are also rejected under 35 USC 112, first paragraph. Specifically, since preparation of a composition to "prevent" dental hypersensitivity is not a credible asserted utility or a well established utility for the reasons set forth above, the instant specification fails to provide an adequate written description to one skilled in the art how to make the claimed compositions capable of achieving that utility.

These rejections can be overcome by changing the term "prevent", e.g. at the fifth line of claim 1, to --- inhibit ---

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) The percent by weight values used throughout the claims are indefinite insofar as the claims do not specify the basis for their determination, e.g. percent by weight based on the total weight of the composition, percent by weight based on the weight of the tooth bleaching compound, percent by weight based on the combined weights of bleaching compound and potassium-containing compound, etc. See Honeywell Intl., Inc. v. Intl. Trade Commn., 341 F.3d 1332, 1340 (Fed. Cir. 2003). (Holding that, where a claimed value varies with its method of measurement, and several alternative methods of measurement are available, the claimed value is indefinite without knowing which method of measurement was used).

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2) The term "high" viscosity in claims 11 and 12 is a relative term which renders the claim indefinite. The term "high" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Anticipation Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 9-12, 14-16, 23 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Jensen et al (USP 6,306,370).

Patentee discloses tooth bleaching gels for reducing tooth sensitivity comprising potassium nitrate and a peroxide bleaching agent. Working example 2 at col. 14 discloses a composition containing all the components recited by the instant claims, in percentages substantially overlapping those required therein, fully anticipating the instantly rejected claims. (Claims 14 and 15 are anticipated by glycerin, which is both a flavoring and sweetening agent – see col. 8, lines 34 and 35 of the prior art). The prior art compositions do not contain abrasives and are not toothpastes (dentrifices): see col. 6, lines 22-24.

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen et al (USP 6,306,370).

The prior art is discussed in the "Anticipation" section above and differs from the instant claims insofar as it does not specifically disclose a composition containing 30 to 40 percent by weight glycerin, and 30 to 35 percent by weight propylene glycol. A composition is exemplified that contains 57.35 percent glycerin and 20 percent propylene glycol in working example 7 at col. 16. Patent claim 7 recites glycerin, propylene glycol, and "mixtures thereof", and the specification teaches at col. 8, lines 25-28 that "glycerin, polyol or like substance" can be used within the range of 15 to 85 percent of the total bleaching composition.

Thus, the prior art specifically describes mixtures of glycerin and propylene glycol, and suggests the mixture in total can comprise anywhere from 15 to 85 percent of the overall composition. Accordingly, it would have been obvious to have operated within these disclosed parameters, and to have selected

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mixtures having weight percentages of glycerin and propylene glycol falling within the instant values, motivated by the desire to optimize performance for a particular given formulation. As stated by the Federal Circuit in a recent decision, "the normal desire of scientists or artisans to improve upon what is generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." In re Peterson, 315 F.3d 1325 (C.A. Fed. 2003).

2) Claims 8, 13, 17, 22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen et al (USP 6,306,370) in view of Norfleet et al (USP 5,486,350).

The primary reference is discussed in the "Anticipation" section above and differs from the instant claims insofar as it discloses incorporating potassium nitrate into non-toothpaste (non-dentifrice) gels to inhibit hypersensitivity, but it does not disclose other inhibitors such as potassium citrate and potassium oxalate, as required by instant claims 8, 17, 22 and 25.

The secondary reference discloses dental compositions containing potassium nitrate, potassium citrate, or potassium oxalate, in amounts ranging from 1 to 15 percent, as hypersensitivity inhibitors. See col. 7, lines 59-67. It specifically teaches that such inhibitors may be used in non-toothpaste (non-dentifrice) gels: see col. 7, line 7. It differs from the instant claims insofar as, although it briefly mentions "per-compound" bleaching agents in a laundry list of potential additives at col. 6, lines 41 and 42, it does not provide sufficient direction to "pick and choose" such additives to be anticipatory.

It would have been obvious to have used potassium citrate or potassium oxalate in place of the potassium nitrate inhibitor disclosed by the primary reference, motivated by the teaching of equivalency for that function provided by the secondary reference. There are many sound technical reasons for using a potassium nitrate inhibitor other than potassium nitrate, e.g. to avoid degradation of certain components due the presence of nitrate.

The primary reference teaches that examples of "thickening agents that can assist other tackifying agents", i.e. the preferred carboxypolymethylene tackifier, include various carbohydrate gums or "any compositional or chemical equivalents of the foregoing." See col. 3, lines 40-51. It thus differs from instant claim 13 insofar as it does not specify hydroxyalkyl celluloses.

The secondary reference clearly teaches that hydroxyalkyl celluloses are "compositional equivalents" of carbohydrate gums as thickening agents for dental gels. See col. 5, lines 11-23. Accordingly, it would have been obvious to have used a hydroxyalkyl cellulose as a thickener in the primary reference compositions, motivated by the teaching of equivalency for that function provided by the secondary reference. There are many sound technical reasons to provide a modifier for use with carboxypolymethylene ("Carbopol"), e.g. to render a particular composition less hygroscopic, to reduce acidity, etc.

3) Claims 1-17 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer (USP 5,098,303) in view of Norfleet et al (USP 5,486,350).

The primary reference discloses tooth bleaching gels comprising peroxide bleaching agents, but which do not contain abrasives and thus are not toothpastes (dentrifices). Working example 1 discloses a composition containing all the preferred components of instant claim 9, in percentages substantially overlapping those required instantly, except that a potassium-containing inhibitor is not included. Again, glycerin is both a sweetener and a flavoring agent as required by instant claims 14 and 15. The primary reference thus differs from the instant claims as follows:

- i) it does not disclose using a potassium-containing compound to reduce hypersensitivity;
- ii) it does not disclose using a hydroxyalkylcellulose as required by instant claim 13.

The primary reference does recognize what is well-known in the art, namely that one of the disadvantages of conventional tooth bleaching processes is the induction of hypersensitivity, especially at sites where dentin is exposed. See col. 9, lines 3-7.

The secondary reference discloses dental compositions containing potassium nitrate, potassium citrate, or potassium oxalate, in amounts ranging from 1 to 15 percent, as hypersensitivity inhibitors. See col. 7, lines 59-67. It specifically teaches that such inhibitors may be used in non-toothpaste (non-dentrifice) gels: see col. 7, line 7. It differs from the instant claims insofar as, although it briefly mentions "per-compound" bleaching agents in a laundry list of potential additives at col. 6, lines 41 and 42, it does not provide sufficient direction to "pick and choose" such additives as to be anticipatory.

It would have been obvious to have included 1-15 percent potassium nitrate, potassium citrate or potassium oxalate in the tooth bleaching gels of the primary reference, motivated by the desire to inhibit the development of dental hypersensitivity as taught by the secondary reference.

4) Claims 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer (USP 5,098,303) in view of Norfleet (USP 5,486,350), the combination being taken further in view of in view of Velluci (USP 4,294,894).

The primary and secondary references, and the motivation for combining the teachings of their disclosures, are discussed in detail in subsection "3)" supra. The combined teachings of the primary and secondary references differ from the instant claims insofar as compositions containing 30 to 40 percent glycerin and 30 to 35 percent propylene glycol are not specifically disclosed. The primary reference does teach at col. 6, lines 61-65 that 20 to 70 percent glycerin may be used as a carrier, and further teaches, at the first two lines of col. 7, that "other polyols" may be used as a substitute for glycerin.

The tertiary reference teaches what is well-known in the art, namely that the use of propylene glycol as carrier in oral care compositions is conventional, either alone or in admixture with glycerin. See col. 3, lines 2-6. The reference is cited to demonstrate the general state of the art, and thus differs from the instant claims insofar as it does not disclose the particular compositions recited therein.

It would have been obvious to have used propylene glycol as a partial replacement for glycerin in the compositions suggested by the combined teachings of the primary and secondary references, motivated by the desire to modify particular compositions to tailor them to have particular optimal and/or desired physical characteristics, since such modification is routine in the art as taught by the tertiary reference. Having arrived at that combination, it would have been obvious to have operated within the overall percentage range of 20 to 70 percent provided by the primary reference, selecting mixtures having weight percentages of glycerin and propylene glycol falling within the instant values, motivated by the desire to optimize performance for a particular given formulation. As stated by the Federal Circuit in a recent decision, "the normal desire of scientists or artisans to improve upon what is generally known

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provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." In re Peterson, 315 F.3d 1325 (C.A. Fed. 2003).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 6:30-3:00PM;
Tuesday: 10-6:30PM;
Wednesday: off;
Thursday: 10-6:30PM; and
Friday: 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614

